



06-10-09

Attorney Docket No.: 23854-0004US1

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Hasse Roland Abrahamsson et al. Art Unit : 1614  
Patent No. : 7,514,421 Examiner : Phyllis G. Spivack  
Issue Date : April 7, 2009 Conf. No. : 6477  
Serial No. : 10/551,999  
Filed (371(c)) : October 4, 2005  
International Filing Date: April 1, 2004  
Title : USE OF AN IBAT INHIBITOR FOR THE TREATMENT OF PROPHYLAXIS  
OF CONSTIPATION

**Mail Stop Petition**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT**  
**UNDER 37 C.F.R. § 1.705(d)**

Sir:

Applicant hereby requests reconsideration of the Patent Term Adjustment (PTA) of 0 days awarded U.S. Patent No. 7,514,421 referenced above. The PTA of 0 days was specified on the Issue Notification, mailed March 18, 2009 in connection with the above-referenced patent, and also on the face page of U.S. Patent No. 7,514,421, as issued on April 7, 2009. Applicant believes that the correct PTA is 970 days and, therefore, requests an additional 970 days of PTA to be applied to the above-referenced patent.

The instant request is predicated at least in part on the decision *Wyeth v. Dudas* (*Wyeth et al. v. Jon W. Dudas*, U.S. District Court, D.C., CA No. 07-1492, Mem. Op. September 30, 2008), which holds that methods adopted by the U.S. Patent and Trademark Office (PTO)'s for calculating the PTA may be incorrect in certain instances where more than three (3) years have elapsed between an application's filing date and issuance of a patent thereon.

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June 8, 2009

Date of Deposit

Applicant submits the instant request for reconsideration is timely, being filed on or before expiry of two months from the issue date of the above-identified U.S. Patent (March 17, 2009); said expiry falling on a weekend, the instant request is timely, being filed on the first business day thereafter. The instant request is timely also because it raises only issues that, per 37 C.F.R. § 1.705(d), were not (and could not have been) raised under 37 C.F.R. § 1.705(b) as of the mailing date of the notice of allowance in the above-referenced application.

### **Applicable Law**

The instant request, filed under 37 C.F.R. § 1.705(d), requests reconsideration of the PTA based in part on an incorrect assessment, by the PTO, of PTA where more than three (3) years have elapsed between filing date and issuance of a patent. As such, the instant request could not have been presented prior to issuance of the patent (for example, at time of payment of issue fee, as would be a request under 37 C.F.R. § 1.705(b)), when the actual issue date of the patent would not have been known.

Prior to the issue date of the above-referenced patent, the U.S. District Court for the District of Columbia, in *Wyeth v. Dudas*, held that the PTO's method for calculating the PTA in patents that issue more than three years after their respective filing dates was in error. Applicant believes that since the decision in *Wyeth v. Dudas* became public prior to the date on which the issue fee was paid in the above-identified application, the PTO had an opportunity to apply the method of calculating PTA as set forth in that decision to the above-referenced patent. Because the PTO did not do that, Applicant now requests that the PTO apply the statutory interpretation set forth in *Wyeth v. Dudas* to U.S. Patent No. 7,514,421, and accord additional PTA as calculated herein.

According to *Wyeth v. Dudas*, the correct reading of 35 U.S.C. § 154(b)(1)(B) ("GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY"), is that the number of days delay (beyond three years) in issuance of the patent is counted from the day after 3-years from the filing date of the application on which the patent is granted (and extends until the earlier of date of grant of the patent or the filing of a Request for Continued Examination (RCE)). Furthermore, according to *Wyeth v. Dudas*, the correct reading of the provision of 35

U.S.C. § 154(b)(2)(A) (that various periods of delay should not overlap), is that periods of delay attributable to the PTO under 35 U.S.C. § 154(b)(1)(A) (that occur *prior to* three (3) years elapsing from the application's filing date) do not overlap with the period under 35 U.S.C. § 154(b)(1)(B) (which is measured from three (3) years *after* the application's filing date).

### **Statement of Facts**

Per 37 C.F.R. § 1.705(d) (referencing 37 C.F.R. § 1.705(b)(2)(i,ii)), Applicant now sets forth the relevant time periods in the above-referenced application, as basis for requesting that an additional PTA of 970 days be awarded U.S. Patent No. 7,514,421.

First, Applicant respectfully submits that the PTO has been using the wrong filing date of the application for purposes of calculating PTA. The instant application (serial no. 10/551,999) is a national phase of an international application having an international filing date of April 1, 2004. This date is the filing date of the application for all purposes. 35 U.S.C. § 363. Notwithstanding the provisions of 35 U.S.C. §§ 154(b)(1)(A)(i)(II) and 154(b)(1)(B), Applicant believes that the failure to use the international filing date of the application for the purposes of calculating PTA is inconsistent with the terms of 35 U.S.C. § 363. Accordingly, the filing date for the purposes of calculating PTA is April 1, 2004, and not October 4, 2005 (date of completion of requirements under 35 U.S.C. § 371).

#### ***PTO Delay***

The date that is fourteen (14) months after the filing date of the instant application is June 1, 2005.

A first office action (Non-Final Rejection) was mailed May 2, 2007. PTA accrues to Applicant, under 35 U.S.C. § 154(b)(1)(A)(i), for each day after 14 months from the application's filing date until a first office action is mailed. Accordingly, PTA accrues from June 1, 2005 up to May 2, 2007, comprising a total of 701 days in Applicant's favor. (This is an "A" delay, in the language of the *Wyeth* opinion.)

Three years from the filing date of the instant application is April 1, 2007. The instant patent issued on April 7, 2009, after an RCE was filed on September 15, 2008. Accordingly, the PTA accruing to Applicant under 35 U.S.C. § 154(b)(1)(B), for PTO delays beyond three years

Inventor(s): Hasse Roland Abrahamsson et al.  
Patent No. : 7,514,421  
Issued : April 7, 2009  
Serial No. : 10/551,999  
Filed : October 4, 2005  
Page : 4 of 5

Attorney Docket No.: 23854-0004US1

in issuing a patent, is measured from April 1, 2007 to September 15, 2008, and is 533 days.

(This is a "B" delay, in the language of the *Wyeth* opinion.)

Accordingly, the total PTO delay in granting the above-referenced patent is 1234 days because, according to *Wyeth*, the "A" delays do not overlap with, or offset, the "B" delays.

*Applicant Delay*

The PTO delay calculated hereinabove, is offset by three periods of Applicant delay, as follows:

Applicant responded to the May 2, 2007 Non-Final Action on July 27, 2007, but the response was deemed "non-responsive" by the PTO; a complete response was not filed until December 10, 2007. Applicant delay should be therefore be measured from August 2, 2007 (the 3-month date for response to the office action) to December 10, 2007, a period of 142 days of delay under 35 U.S.C. § 154(b)(2)(C)(ii). (The PTO calculation, 136 days, appears to be an under-estimate.)

Applicant responded to the March 4, 2008 Final Action on July 8, 2008 by filing an amendment. An RCE was filed on September 15, 2008 so Applicant incurred 103 days of delay under 35 U.S.C. § 154(b)(2)(C)(ii).

Finally, Applicant filed, on February 12, 2009 a Rule 312 Amendment, to which a Response was mailed on March 3, 2009, thereby incurring 19 days of delay under 35 U.S.C. § 154(b)(2)(C)(ii). (The PTO calculation, 20 days, appears to be an over-estimate.)

Accordingly, the total Applicant delay in connection with calculating PTA for the above-referenced patent is 264 days.

*Actual PTA accruing to Applicant*

Accordingly, the PTA accruing to Applicant is calculated as 1234 days of PTO delay, less 264 days of Applicant delay, *i.e.*, 970 days of PTA in total.

The Issue Notification, mailed February 25, 2009, indicated that the Patent Term Adjustment is only 0 days. The patent, U.S. Patent No. 7,514,421, issued on April 7, 2009, with a PTA awarded of 0 days.

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Issued : April 7, 2009  
Serial No. : 10/551,999  
Filed : October 4, 2005  
Page : 5 of 5

Attorney Docket No.: 23854-0004US1

### *Summary*

Accordingly, Applicant now requests that an ADDITIONAL 970 DAYS OF PTA be accorded to U.S. Patent No. 7,514,421, giving a TOTAL PTA of 970 days.

Furthermore, in compliance with 37 C.F.R. § 1.705(d) (referencing 37 C.F.R. § 1.705(b)(2)), Applicant asserts that:

1. U.S. Patent No. 7,514,421 is not subject to a terminal disclaimer, and
2. Applicant did not fail to engage in reasonable efforts to conclude processing of the application on which that patent was granted.

Applicant reserves the right, under 35 U.S.C. 154(b)(4), to file a civil action against the Director of the PTO to request review of the PTA awarded the above-referenced patent, in the United States District Court for the District of Columbia, within 180 days after the grant of the above-identified patent, even in the absence of an adjudication of the instant request before that time.

The instant petition is timely, being filed on the first business day after two months from the issue date of the patent.

### Fee Authorization

In compliance with 37 C.F.R. § 1.705(d) (referencing 37 C.F.R. § 1.705(b)(1)), Applicant hereby authorizes payment of the fee of \$200, under 37 C.F.R. § 1.18(e) to deposit account number 06-1050 (referencing docket no. 23854-0004US1). No other fee is believed due with this response. However, should the Commissioner determine otherwise, he is authorized to charge any additional fee(s) associated with this communication, or to credit any overpayment to, our deposit account number 06-1050 (attorney docket no. 23854-0004US1).

Respectfully submitted,

Date: June 8, 2009

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